

14. A sterilization indicator according to claim 1, wherein the sterilant-resistant chemical comprises tetraglycerol monostearate.

15. A sterilization indicator according to claim 1, wherein the sterilant-resistant chemical comprises glycerol-7-diisononanoate.

16. A sterilization indicator for testing the effectiveness of a sterilization procedure, comprising:

- (a) a compressible outer container having at least one opening to allow sterilant to enter the outer container during the sterilization procedure;
- (b) a source of an active enzyme contained within the outer container, the enzyme having an enzyme activity that is correlated with the survival of at least one test microorganism commonly used to monitor the effectiveness of a sterilization procedure, wherein the enzyme is substantially inactivated by a sterilization procedure that is lethal to the test microorganism, but wherein the enzyme may not be substantially inactivated by a sterilization procedure that is sublethal to the test microorganism;
- (c) a sterilant-resistant chemical associated with the source of active enzyme in such a manner that the active enzyme is more resistant to inactivation by a sterilization procedure than it would be if it were not associated with the sterilant-resistant chemical; and
- (d) a breakable inner container within the outer container that is impermeable to the sterilant used in the sterilization procedure and that contains a substrate, wherein the inner container is adapted so that it may be broken by compressing the outer container, to allow the substrate to contact the enzyme, and wherein the substrate is capable of reacting with active enzyme to form an enzyme-modified product that provides a detectable indication of the failure of a sterilization procedure.

17. A sterilization indicator according to claim 16, wherein the substrate is contained within the inner container.

18. A sterilization indicator according to claim 16, wherein the source of an active enzyme comprises a microorganism.

5 19. A sterilization indicator according to claim 18, wherein the source of an active enzyme comprises *Bacillus stearothermophilus* spores.

20. A sterilization indicator according to claim 16, wherein the source of an active enzyme comprises a purified enzyme.

10 21. A sterilization indicator according to claim 16, wherein the sterilant-resistant chemical comprises a surfactant.

15 22. A sterilization indicator according to claim 21, wherein the sterilant-resistant chemical further comprises a surfactant and a hydrophobic additive.

23. A sterilization indicator according to claim 16, wherein the sterilant-resistant chemical comprises a polyglycerol alkyl ester or a polyglycerol alkyl ether.

20 24. A sterilization indicator according to claim 23, wherein the sterilant-resistant chemical is a compound selected from the group consisting of decaglyceryl monostearate, hexaglyceryl monostearate, tetraglyceryl monostearate, hexaglyceryl polyricinolate, decaglyceryl monolaurate, hexaglyceryl monolaurate, tetraglyceryl monolaurate, decaglyceryl trioleate, decaglyceryl monooleate, decaglyceryl dipalmitate, hexaglyceryl distearate, decaglyceryl monooleate, decaglyceryl monomyristate, 25 decaglyceryl monoisostearate, and decaglyceryl diisostearate, and mixtures of two or more members of the group.

30 25. A sterilization indicator according to claim 16, wherein the sterilant-resistant chemical comprises an ethoxylated polyhydric alcohol ester or an ethoxylated polyhydric alcohol ether.

26. A sterilization indicator according to claim 25, wherein the sterilant-resistant chemical is a compound selected from the group consisting of glycereth-7-diisononanoate, polyoxyethylene (5) glyceryl monostearate, and mixtures of two or members of the group.

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27. A sterilization indicator according to claim 16, wherein the sterilant-resistant chemical comprises decaglycerol.

28. A method for testing the effectiveness of a sterilization procedure, comprising the steps of:

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- (a) providing a source of an active enzyme having an enzyme activity that is correlated with the survival of at least one test microorganism commonly used to monitor the effectiveness of a sterilization procedure, wherein the enzyme is substantially inactivated by a sterilization procedure that is lethal to the test microorganism, but wherein the enzyme may not be substantially inactivated by a sterilization procedure that is sublethal to the test microorganism;
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- (b) treating the source of active enzyme with a sterilant-resistant chemical so that the enzyme is more resistant to inactivation by a sterilization procedure than it would be if it were not associated with the sterilant-resistant chemical;
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- (c) providing a substrate that is capable of reacting with the active enzyme to form an enzyme-modified product to provide a detectable indication of the failure of a sterilization procedure;
- (d) subjecting the source of active enzyme that has been treated with a sterilant-resistant chemical to a sterilization procedure;
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- (e) combining the enzyme and substrate; and
- (f) examining the sterilization indicator for a detectable signal.

29. A sterilization indicator for testing the effectiveness of a hydrogen peroxide plasma sterilization procedure, comprising:

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- (a) a source of active enzyme having an enzyme activity that is correlated with the survival of at least one test microorganism commonly used to monitor the